

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

**COLUMBIA UNIVERSITY'S REPORT TO THE COURT
PURSUANT TO ORDER DATED MAY 17, 2005**

In its Order dated May 17, 2005 ("May 17 Order"), the Court requested the parties to meet and confer and thereafter file proposed Orders in each case dismissing those claims that the parties agree should be dismissed pursuant to its Memorandum and Order dated November 5, 2004 ("November 5 Order"). The parties have conferred and filed proposed Orders dismissing the claims that the parties agree should be dismissed. There is a disagreement, however, as to (i) whether Amgen's first, third, and seventh claims for relief survive the November 5 Order; (ii) whether Biogen and Genzyme's first and fifth claims for relief survive the November 5 Order; and (iii) whether Wyeth's fourth, fifth, and sixth claims for relief survive the November 5 Order. Columbia has filed herewith a proposed Order dismissing these claims as well.

The May 17 Order also requested the parties to meet and confer and thereafter respond to a series of questions listed in paragraph 2 of the Order. Below are Columbia's responses to the Court's questions.

A. Whether Amgen's first and seventh claims survive the November 5 Order because they alleged that Columbia University is seeking royalties on the basis of the original Axel patents.

Amgen's First and Seventh Claims for relief do not survive the Court's November 5 Order because those claims are not based, as Amgen now alleges, on a demand for royalties under the original Axel patents, nor did Amgen ever argue otherwise until long after this Court granted Columbia's motion to dismiss.

Amgen's First Claim for Relief

Amgen's Second Amended Complaint ("SAC") alleges that, following the expiration of the original Axel patents in August 2000, Columbia demanded continued royalties from Amgen on the basis of its then-pending patent applications. In particular, Amgen's pleading alleges that "Columbia had pending patent applications after August 16, 2000, as a result of which Columbia demanded that Amgen pay royalties on sales after August 16, 2000." SAC, ¶ 58(b). Amgen's First Claim for Relief reiterates this allegation, stating that "Columbia contends that Amgen must pay royalties and fees for periods after August 16, 2000 because, *inter alia*, claims in pending patent applications, including the application leading to the '275 patent, were pending after August 16, 2000," and that "Amgen contends that it is not required to pay royalties and fees for periods after August 16, 2000 because, *inter alia*, the pendency of those applications does not result in Amgen's products qualifying as Licensed Products the sale of which would trigger a royalty obligation under the License Agreement, Exhibit E." SAC, ¶ 62.

Nowhere in Amgen's First Claim for Relief is there any allegation that it is based on a demand for royalties under the original Axel patents, nor can Amgen's SAC fairly be read to include such an allegation. Indeed, in the face of an omnibus motion to dismiss, Amgen never argued that this declaratory relief claim pertained in any way to a demand for royalties under the

original Axel patents. The *first* time Amgen made that assertion was *after* the Court granted Columbia's motion to dismiss. *See* Docket No. 179, Joint Report To The Court Pursuant To Order Dated November 5, 2004, at 2. If Amgen sincerely believed that its First Claim for Relief was designed to cover a demand for royalties under the original Axel patents, it would have—and should have—made this argument in a timely manner, rather than raising it as an afterthought in the wake of the Court's order granting Columbia's motion.

Amgen's efforts to transform and salvage its First Claim for Relief should be rejected as untimely, unfair to Columbia and the Court, and unsupported by Amgen's pleadings.

Amgen's Seventh Claim for Relief

In opposing Columbia's omnibus motion to dismiss, Amgen never even *mentioned* the Seventh Claim for Relief in its opposition motion, or during the hearing on the motion. The only claims that Amgen urged should survive were the First Claim for Relief (on grounds that were squarely rejected by the Court) and its claim for attorney's fees (also squarely rejected by the Court). *See* Docket No. 113, Memorandum of Plaintiffs Amgen Inc. and Immunex Corporation in Opposition to Columbia University's "Emergency Motion to Dismiss for Lack of Subject Matter Jurisdiction," filed Sept. 22, 2004, at 13-14. Never did Amgen raise the Seventh Claim for Relief, and the Court should not permit Amgen to do so now, after the Court has ruled.

Even if the Court were willing to consider this thirteenth-hour argument by Amgen, it should, in any event, be summarily rejected. Amgen's Seventh Claim for Relief asserts that Columbia engaged in "repressive practices," a claim that Judge Pfaelzer noted was "*unlikely to survive a dispositive motion*," but the only allegation that Amgen has ever pointed to in this regard is the claim that Columbia sought royalty payments on the basis of pending patent applications, as alleged in ¶ 58(b) and as discussed above. [Docket No. 185, Ex. A at 6.] Columbia committed in writing not to seek royalties on pending applications (unless and until

they mature into issued patents) on March 9, 2004. Thus, there is no longer any controversy between the parties regarding payments on pending patent applications.

Columbia has made it excruciatingly clear to all the plaintiffs that it is not seeking royalties on the '275 patent as it currently exists, or on any pending patent application. Amgen has not ever alleged otherwise, and thus all of its claims should be dismissed.

This issue is discussed in Section A(1)(b) of the Joint Report To The Court Pursuant To Order Dated November 5, 2004. [Docket No. 179, at 5-7.]

B. Whether Biogen Idec MA's first claim survives the November 5 Order because it alleges that Columbia improperly terminated its license.

The first claim seeks a declaration that Biogen Idec MA, Genzyme, and Abbott "have no obligation to pay . . . royalties because . . . the '275 patent is invalid and unenforceable." In its November 5 Order, the Court determined that Columbia's covenant not to sue completely eliminates any reasonable apprehension that plaintiffs will face a suit for infringement of the '275 patent and therefore destroys the existence of subject matter jurisdiction over plaintiffs' declaratory judgment claims. November 5 Order, at 15. In addition, the Court concluded that, even if a controversy were to exist between the parties, "this court would exercise its discretion to dismiss the requests for declaratory judgment" because of the substantial judicial resources it would have to expend to adjudicate plaintiffs' claims. *Id.*, at 25-28.

Abbott agrees that the Court's November 5 Order dismisses the first claim (and all of Abbott's other claims). On the other hand, Biogen Idec MA and Genzyme refuse to accept the dismissal of the first claim, as well as the fifth claim (seeking a declaration of exceptional case). They suggest that the question of the validity and enforceability of the '275 patent is still relevant because of their claim that Columbia wrongfully terminated their license agreements.

There is no allegation of wrongful termination in the first claim. The first claim is a request for a declaratory judgment, nothing more. The first claim seeks no other relief. Indeed, in an effort to justify their filing of a second action instead of moving to amend their complaint in their original action, Biogen Idec MA and Genzyme have both represented to the Court that there is no breach of contract count in the original action.¹ Because the first claim merely seeks declaratory relief, it is covered by Columbia's Covenant Not to Sue and therefore should be dismissed pursuant to the November 5 Order. In addition, in light of the dismissal of all declaratory relief claims relating to the validity or enforceability of the '275 patent, the fifth claim should be dismissed, too.

This issue is discussed in Section C(2)(c) of the Joint Report To The Court Pursuant To Order Dated November 5, 2004. [Docket No. 179, at 13-15.]

C. Whether Wyeth's fourth, fifth, and sixth claims survive the November 5 Order because they state causes of action for recovery of past sums.

The fourth and fifth claims seek declarations that Wyeth and Genetics Institute have no obligation to pay royalties based on the '275 patent, or based on pending patent applications. The sixth claim seeks a declaration that the '275 patent is unenforceable. On March 9, 2004, Columbia committed in writing not to seek royalties based on pending patent applications (unless and until they mature into issued patents). Columbia also covenanted not to sue Wyeth

¹ Docket No. 8, Case No. 04-CV-12009 MLW, Opposition of Biogen Idec Inc., Biogen Idec MA, Inc. and Genzyme Corporation To Columbia University's Motion To Dismiss, at 2 ("The new complaint also alleges several new claims on behalf of Biogen and Genzyme, . . . namely . . . breach of contract By filing this new action, plaintiffs did not intend to duplicate pending claims [in the original action]"); Docket No. 90, Case No. 03-CV-11329 MLW, Memorandum in Support of Motion of Biogen Idec MA Inc. and Genzyme Corporation For Consolidation of New Related Case, at 2 ("The new complaint also alleges several new claims on behalf of . . . Biogen and Genzyme, . . . namely . . . breach of contract").

and Genetics Institute based on the '275 patent. In light of these covenants, Wyeth and Genetics Institute have no reasonable apprehension of suit based on the '275 patent or based on any pending patent applications. The Court should therefore dismiss these claims for lack of subject matter jurisdiction.

In an attempt to avoid the consequences of the November 5 Order, Wyeth and Genetics Institute now argue that their fourth, fifth, and sixth claims are actually contract claims for the refund of payments made to Columbia. This argument is entirely inconsistent with the language of these claims. Indeed, there is no clearer evidence that the fourth, fifth, and sixth claims are not contract claims than the fact that Wyeth and Genetics Institute have moved to amend their complaint to add a specific claim for the refund of payments. [Docket No. 178, Ex. A at 35-36.]

This issue is discussed in Section A(4)(a) of the Joint Report To The Court Pursuant To Order Dated November 5, 2004. [Docket No. 179, at 9-11.]

D. Whether Genentech's fifth claim should be remanded to the Northern District of California.

Genentech's fifth claim purports to state a claim for breach of contract based on the alleged wrongful termination of its license agreement with Columbia. On March 18, 2004, Columbia sent a letter terminating the license agreement for failure to pay royalties due under the '275 patent and for failure to permit Columbia to exercise its contractual right to audit Genentech. Columbia subsequently withdrew the termination based on the '275 patent. Accordingly, the only issue in the fifth claim is whether Columbia's termination of Genentech's license agreement for failure to allow an audit constitutes a breach of contract. This dispute involves facts unique to Genentech and has no relation to any of the other cases in the

multidistrict litigation. Accordingly, this claim should be remanded to the Northern District of California.

E. Whether Amgen and Wyeth should be granted leave to amend their complaints.

Wyeth/Genetics Institute

Wyeth, Genetics Institute, and Columbia are in very productive settlement negotiations. To facilitate these negotiations, the parties filed joint motions asking the Court to extend Columbia's time to respond to the Wyeth and Genetics Institute motion to amend until July 1, 2005. The Court has not acted on these recent pending requests. Columbia is optimistic that the parties will conclude their settlement before July 1. In the unlikely event that the parties are unable to conclude their settlement, Columbia intends to oppose the motion to amend.

Amgen/Immunex

Amgen should not be permitted to file a fourth pleading in this action because it is untimely and flatly contrary to this Court's and Judge Pfaelzer's earlier rulings in this case.

It is undisputed that Amgen filed its motion to amend certain of its declaratory relief claims *after* the Court granted Columbia's motion to dismiss those claims. If the Court determines that the First and Seventh Claims for Relief were within the scope of that order, as discussed above, then Amgen's motion should be denied for the simple reason that those claims have already been dismissed.

Even if, however, this Court reaches the merits of Amgen's motion to amend, the motion should be denied. Amgen has filed *three* complaints in this action, all originally in the Central District of California, and now proposes to file its *fourth*. When the Central District of California permitted the filing of Amgen's Second Amended Complaint, the district judge *specifically*

ordered that no further amendments shall be permitted, a fact that Amgen did not disclose in its motion to amend. [Docket No. 185, Ex. A at 7 n.2.]

Indeed, at the hearing on Columbia's motion to dismiss, Amgen sought the Court's approval to amend its pleading to add the claims of its corporate affiliates. The Court specifically rejected such a filing as untimely and told Amgen's counsel:

No, at this point, *you can't move to amend*. You've had the briefing and the motion to dismiss . . . So I'm going to decide the case on the record as it now stands.

10/6/04 Hearing, at 130-131 (emphasis added). If it was too late for Amgen to amend to bring in a new party with a new claim, then it inexorably follows that, the Court having now ruled on the motion to dismiss, it is too late for an *existing* party to file what would be its *fourth* pleading in this matter in order to avoid the ramifications of that order of dismissal.

This issue is discussed in Section A(1)(b) of the Joint Report To The Court Pursuant To Order Dated November 5, 2004. [Docket No. 179, at 7.]

F. Whether Amgen and Biogen should be allowed to consolidate their new complaints with whatever portions of their MDL cases survive the November 5 Order.

Amgen

Because the Amgen Affiliates have never been under any express or implied threat of an infringement suit on the '275 patent, Columbia moved to dismiss all claims in the Amgen Affiliate lawsuit based on lack of subject matter jurisdiction. That motion has been fully briefed and is pending before the Court. If Columbia's motion to dismiss is granted, there will be nothing left of the new Amgen Affiliate suit to consolidate with the MDL litigation.

Moreover, all of the claims of the Amgen Affiliate suit are based on the '275 patent. Those claims, therefore, mirror the claims of the MDL litigation that *have now been dismissed*

by the November 5 Order. Because the Amgen Affiliate claims do not overlap with the surviving MDL claims, consolidation will not result in efficiencies and will not simplify the issues presented for the Court.

Even if the Court determines that some portion of the MDL litigation or the Amgen Affiliate suit survives each of the pending motions and should be consolidated, Amgen's arguments that the Affiliate suit should be consolidated for all purposes, including trial, must be flatly rejected under binding Supreme Court authority. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 40 (1998).

Biogen

Because the November 5 Order dismisses all claims in the original action, there is nothing to consolidate with the second action. In addition, even if some part of the original action were to survive the November 5 Order, any consideration of consolidation should await Columbia's pending motions to dismiss in the second action.

G. Whether, if part of Amgen's case remains, either because it was not resolved by the November 5 Order, or because the Court has granted Amgen leave to amend its complaint, it should be remanded.

The express basis for the transfer order by the JPML was the presence of common questions relating to the validity and enforceability of the '275 patent. These common questions no longer exist, let alone predominate.

Of all the plaintiffs in this action, *only* Amgen took the position that it did not have to pay Columbia—pursuant to its license to the original Axel patents—for product manufactured before the expiration of the original Axel patents, but sold after that date. As a result, Amgen is the only plaintiff that Columbia is countersuing for payment of back royalties. This issue is not

raised in any other lawsuit with any other plaintiff, and has no relationship whatsoever to the validity or enforceability of the '275 patent, nor does Amgen claim otherwise.

The only claims that remain in this action are Columbia's counterclaims seeking more than \$100 million in back royalties under Columbia's now-expired, original Axel patents. Even if the Court were to find that Amgen's First and Seventh Claims for Relief survive the motion to dismiss, Amgen has made it clear that these purported claims—as they now conveniently construe them—are simply mirror images of their defenses to Columbia's counterclaims.

Given the unique posture of the Amgen litigation, and the lack of any common issue relating to the validity and enforceability of the '275 patent, this Court should enter an order suggesting a remand of this action by the JPML.

This issue is discussed in Section C(1)(b) of the Joint Report To The Court Pursuant To Order Dated November 5, 2004. [Docket No. 179, at 13.]

Respectfully submitted,

/s/ David I. Gindler

Morgan Chu
David I. Gindler
Jason G. Sheasby
Irell & Manella LLP
1800 Ave of the Stars, Suite 900
Los Angeles, CA 90067
(310) 277-1010
(310) 203-7199 (fax)

/s/ Wayne M. Barsky

Wayne M. Barsky
Amanda J. Tessar
Gibson, Dunn & Crutcher LLP
2029 Century Park East
Los Angeles, California
90067-3026
(310) 552-8500
(310) 551-8741 (fax)

Thomas F. Maffei (BBO # 313220)
Scott McConchie (BBO # 634127)
Griesinger, Tighe & Maffei LLP
176 Federal Street
Boston, MA 02210-2600
(617) 542-9900
(617) 542-0900 (fax)

Attorneys for THE TRUSTEES OF
COLUMBIA UNIVERSITY IN THE
CITY OF NEW YORK

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